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October 27, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville, MD 20852

Subject: Proposed Rule and Special Control for Surgeon's and Patient Examination Gloves (Docket No. 98N-03 13)

Safeskin Corporation is responding to the invitation to comment on the Proposed Rule on reclassification and special controls for surgeon's and patient examination gloves, which appeared in the Federal Register of July 30, 1999. For more than ten years, Safeskin has been developing, manufacturing, and marketing surgeon's and patient examination gloves, both powdered and powder free, whether composed of natural rubber latex or of synthetic materials. We appreciate this opportunity to contribute to the discussion on the Proposed Rule and the proposed special control, the Medical Glove Guidance Manual, Although we are taking no position regarding the merits of the reclassification effort itself, we do have recommendations to the proposed labeling, Guidance Manual, and some of the specific questions FDA posed in the Preamble to the Proposed Rule.

I. Proposed Regulation

A. Proposed 2 1 CFR 80 1.440: User labeling for powdered and powder free surgeon's and patient examination gloves.

1. The proposed labeling statement in subsection (a) states in part that "FDA recommends that this product contain no more than 120 mg powder and 1200 µg extractable protein per glove. This product contains no more than [insert level] mg powder and no more than [insert level] µg extractable protein per glove."

a. The recommended powder limit of 120 mg per glove would be better expressed in terms of milligrams per decimeter squared (mg / dm^2). In this case, 120 mg of powder per glove is roughly equivalent to 12 mg/$decimeter^2$. Expressing the powder content in mg/$decimeter^2$ would provide the user with a more accurate representation of how

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powder-laden a glove is. Stating a total powder level of 120 mg for a size 6 glove and also for a size 8 ½ glove may obscure the difference in the relative amounts of powder on each of the gloves, but expressing powder content in mg/decimeter^2 illuminates the difference. If the limit was expressed in these terms, it would also discourage manufacture and release of over-powdered small gloves. For the same reasons, Safeskin recommends that the extractable protein also be expressed in micrograms/decimeter^2 .

b. The labeling statement should also include reference to the test method used, i.e., it should read:

> FDA recommends that this product contain no more than 12 mg/decimeter^2 powder and 1200 µg extractable protein per glove, as determined by ASTM D 6124 and ASTM D 57 12, respectively.

If the ASTM test methods were not used, the manufacturer should describe the test method on the label or in an insert.

c. Regarding the proposed labeling statements for powder free latex gloves or powdered synthetic gloves (proposed 2 1 CFR 801.440 (b) and (c)), Safeskin recommends that the approach to stating powder and protein limits that was described above should also be applied to these subsections.

B. Proposed 21 CFR 801.440 (d): Expiration Dating.

This subsection states in part that

> (3) The expiration date must be supported by stability studies demonstrating acceptable physical and mechanical integrity of the product over the shelf-life of the product from its date of manufacture.

Safeskin believes it would be very difficult for industry to implement, by the projected effective date of the Final Rule, expiration dates that are based on real-time data alone and that are long enough to be acceptable to users. As currently written, this section of the regulation would have the effect of short-dating most product and would lead to unnecessary scrap and shortages. It would pose the same problems for any new products that are developed and thus would delay their introduction.

Safeskin recommends that FDA work with ASTM and industry to develop an acceptable protocol for accelerated dating. The

product could then be released based on the accelerated testing as long as it was in the process of being confirmed by a real-time study.

Lacking this option of accelerated dating, this part of the regulation will create more problems than it attempts to solve. Lacking this option, the only apparent realistic alternative is to extend the effective date of this specific part of the regulation from two years to four years after the publication of the Final Rule. Only this would provide manufacturers with adequate time to achieve dating that would not result in excessive scrap or product shortages.

C. Proposed 21 CFR 878.4461 (a): Surgeon's gloves, powder free (classification identification).

The classification identification includes labeling statement that powder-free surgeon's gloves "may bear a trace amount of glove powder.. . ." The word "trace" may be confusing to the reader. "Residual" may be a better description of what actually remains on the glove, i.e., particulates as well as glove powder. Also, the ASTM Standard Testing Method for Residual Powder on Medical Gloves (ASTM D 6124-97) refers to it as "residual." (This comment also applies to Proposed 21 CFR 880.625 1, Patient examination gloves, powder free.)

II. Proposed Medical Glove Guidance Manual

A. On pages 4-5 and 6- 11, the Manual states that "FDA does not suggests that there is any medical basis for a non-pyrogenic claim for medical gloves, including surgeon's gloves."

Safeskin respectfully suggests that FDA's position appears to be too categorical and unyielding and thus it might discourage new knowledge from being developed and brought forth. Safeskin believes FDA should reflect a more open or neutral position on this subject.

B. On page 6-2, a new labeling requirement is stated which was not mentioned in the draft regulation and which has not appeared in previous editions of this Glove Manual. The paragraph states:

> The label must contain a statement of net quantity of contents in terms of weight, numerical count, or statements of both numerical count and weight. Whichever statement of net quantity of contents is used, it

must be clearly and understandably stated on the label; for example, "100 gloves – packaged by weight."

The second sentence requires manufacturers to specify on the label, "packaged by weight" or "packaged by count." For gloves, both methods of determination always translate to a numerical count regardless of how the contents are determined – by count or weight. If the manufacturer states a net quantity of contents, for example, of 100 gloves, it is guaranteeing the buyer that it is supplying 100 gloves: otherwise it is misbranding the product. So whether the net quantity was calculated by count or by weight is immaterial because the net contents are guaranteed both by the manufacturer's contractual obligations and by the regulations against misbranding. Adding such a labeling requirement would also eliminate flexibility in making changes to the process since labeling changes are time-consuming and involve considerable expense. Therefore, Safeskin recommends that FDA delete this new labeling requirement ("packaged by weight" or "packaged by count") from the proposed Manual.

III. Responses to the Specific Requests for Comments included in the Federal Register Notice

A. Question: Is the timeframe for implementation of the proposed rule appropriate (i.e., two years from the Final Rule)?

Response: Two years is needed given the amount of work involved. However, if FDA does not allow manufacturers to use an accelerated testing protocol to establish initial expiration dating, more time will be required (as discussed in I.B above). In that case, the effective date for the implementation of expiration dating should be extended to four years from the date of publication of the Final Rule.

B. Question: What is the feasibility and desirability of stating the primary ingredients in glove powder in the product labeling?

Response: Although it is feasible to state in the labeling the primary ingredients of the glove powder, Safeskin believes it is not desirable. The package label is already overcrowded with required information. Also, often this information is proprietary information.

C. Question: Please comment on the feasibility of restrictions on the sale of powdered gloves.

Response: The clinical users should determine which type of glove is best suited for their particular needs and those of their patients. FDA should not limit the specific type of glove each clinician may use.

D. Question: Are there feasible alternative approaches to achieve reduced adverse health effects from allergic reactions and foreign body reactions?

Response: Alternatives do currently exist, such as nitrile, vinyl or powder-free natural rubber latex gloves.

E. Question: Should the recommended limits on powder and protein be recommended limits or required limits?

Response: The limits should be required. This would serve to move the entire industry to producing better gloves.

F. Question: Please comment on the availability of accelerated aging stability study protocols which are predictive of glove shelf-life.

Response: Please see the response in Section I.B above.

G. Question: What is the appropriateness of requiring the use of a special air handling system for facilities using powdered gloves with powder levels over 120 mg?

Response: Clinicians are in the best position to determine what measures are necessary for the protection of health care professionals and patients. FDA would be wise to leave such decisions to them.

H. Question: Whether exemptions or variances should be allowed?
Response: No exemptions or variances should be allowed. If any are, it would start to weaken and delay important progress that can be made in guaranteeing the quality and safety of medical gloves.

In conclusion, Safeskin commends FDA's efforts to contribute to safety and quality levels in the glove industry, and we appreciate this opportunity to voice these constructive observations.

Sincerely,

Van N. Johnson (by req)

Van N. Johnson
Vice President, Global Quality Systems

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code: 99D-2335/C10

See Docket Number/Item Code: 98N-0313/C27